UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,825	01/16/2002	Jon P. Duvick	35718/242052(5718-158)	5366

27310 7590 03/24/2004

PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER	
IBRAHIM, MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,825	DUVICK ET AL.	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 09/19/03 in reply to the Office action of 07/01/03 has been entered. Claims 2-5 are pending and are examined. Claims 2-5 have been amended. All previous rejections and objections not set forth below have been withdrawn in view of Applicant's amendments to the claims.

New Matter

Claims 2-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. MPEP 2163.06 states, "If new matter is added to the claims, the Examiner should reject the claims under 35 USC. 112, 1st paragraph-written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

In instantly rejected claims 2 and 5 recite "30 minutes" of a final wash conditions of 0.1XSSC at 60 to 65C. However, support for the limitation "30 minutes" cannot be found in the specification or in the claims as originally filed. Therefore, the limitation is considered to be a new matter. The hybridization conditions recited on page 13, lines 19-28, of the specification are insufficient to provide support for the limitation. Therefore, Applicant is required to delete the new matter in response to this rejection.

Claim Rejections - 35 USC § 112

Claims 2-5 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to isolated nucleotide sequence of SEQ ID NO: 3 or nucleotide sequences encoding SEQ ID NO: 4, expression vectors and host cells comprising said sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office action of 07/01/03. Applicant's arguments filed 09/19/03 have been fully considered but are not deemed persuasive.

Applicant asserts that amended claims that specify high stringency conditions and nucleotide sequences having at least 90% sequence identity with SEQ ID NO: 3, full-length nucleotide sequences comprising any 200 contiguous bases of SEQ ID NO: 3 and encoding a polypeptide having peroxidase activity are supported by enabling disclosure. Applicant argues that guidance for amino acid substitutions that do not affect desired biological activity and guidance to produce nucleotide sequences of the invention are discussed in the instant specification and in Dayhoff et al (1978) cited on page 10, line 2-6, of the specification.

These arguments are not persuasive because the arguments are not commensurate in scope with the rejected claims. The scope of claims encompass nucleotide sequences that vary several nucleotide positions from SEQ ID NO: 3, wherein the sequences encode a polypeptide having the peroxidase activity of SEQ ID NO: 4. The specification and the prior art such as the Dayhoff et al reference merely

provide a general guidance for a single amino acid substitution that do not affect the biological activity of a give protein. However, Applicant points to no specific methods for obtaining the specifically claimed nucleotide sequences. Neither the state of the prior art nor Applicant's working examples reveal evidence that nucleotide sequences having at least 90% sequence identity to SEQ ID NO: 3, nucleotide sequences that hybridize thereto under the hybridization conditions as recited in the claims, and nucleotide sequences comprising every 200 contiguous bases of SEQ ID NO: 3 would encode a polypeptide having the peroxidase activity of SEQ ID NO: 4. Substantial guidance is required with respect to how and where SEQ ID NO: 3 can be modified so as nucleotide sequences having both the structural and functional characteristics as recited in the claims can be obtained. In addition, the specification discloses seventeen other nucleotide sequences from maize identified as peroxidase encoding sequences. However, none of these sequences have been shown to possess the structural and functional properties as recited in the claims.

With respect to Lazar and Broun et al, the references were relied upon because they teach unpredictability both in determining protein function by sequence identity alone and in amino acid modifications that retain protein function. Lazar showed that the conservative substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while non-conservative substitutions with alanine or asparagine retained the protein function. Broun et al teach a change of as few as four amino acids converts an oleate 12-desaturase to a hydrolase. Applicant's claimed invention includes modifications by multiple substitutions

and/or deletions of nucleotides anywhere along the entire length of SEQ ID NO: 3. Applicant fails to teach any domain analysis or how and where SEQ ID NO: 3 or 4 can be modified in order to obtain nucleotide sequences having both the structural and functional properties as recited in the claims. Therefore, Applicant's arguments against the applicability of the cited references in the instantly claimed invention are not persuasive.

See *Genentech Inc v. Novo Nordisk A/S* 42 USPQ2d 1001, 1005 (Fed. Cir. 1997). The CAFC stated, "(P)atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable....While every aspect of generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention...". See also *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it states " the scope of enablement must bear a "reasonable correlation" to the scope of the claims. In the instant case, the scope of the claims does not reasonably correlate to the scope of enablement.

Written Description

Claims 2-5 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of

record as set forth in the last Office action of 07/01/03. Applicant's arguments filed 09/19/03 have been fully considered but are not deemed persuasive.

Applicant argues that amended claims that recite nucleotide sequences having at least 90% sequence identity or that hybridize under the specified conditions or full-length nucleotide sequences comprising at least 200 contiguous bases of SEQ ID NO: 3 is sufficient to satisfy the written description requirement because the recited structure is predictable. Applicant also argues that the claims have been amended to recite peroxidase activity, and therefore satisfy the written description requirement. Therefore, Applicant requests the rejection be withdrawn.

These arguments are not persuasive because Applicant has not described a representative number of nucleotide sequences of the genus claimed, as stated in the last Office action.

In order to determine whether a claimed invention meet the written description requirement, it is necessary to understand what Applicant has possession of and what Applicant is claiming. It is clear from the specification that Applicant has in possession SEQ ID NO: 3. Applicant also describes 17 other nucleotide sequences also from maize identified as peroxidase encoding sequences. However, none of these 17 nucleotide sequences from maize has been shown to meet both the structural and functional limitations of the claims, and hence do not provide written description support. The claims are directed to a genus of nucleotide sequences from any source having at least 90% sequence identity to SEQ ID NO: 3, nucleotide sequences that hybridize thereto under the hybridization conditions as recited in the claims, and nucleotide sequences

comprising any 200 contiguous bases of SEQ ID NO: 3, all encoding a polypeptide having peroxidase activity. In addition, Applicant fails to describe any domain analysis or how and where SEQ ID NO: 3 or 4 can be modified in order to obtain the desired promoter sequences. Therefore, Applicant has provided no evidence to support the conclusion that the 90% identity and the hybridizing property as recited in the claims are predictable structures. In addition, substantial variation in structures and function and expected among full-length nucleotide sequences that share any 200 contiguous bases of SEQ ID NO: 3 because every 200 contiguous bases of SEQ ID NO: 3 has not been shown to encode a full-length peroxidase. Absent further description, a mere recitation of structural and functional limitations in the claims would not satisfy the written description requirement.

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus". (43 USPQ2d at 1406). See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism (The *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997).

For the reasons discussed above and in the last Office action, the claimed invention is not adequately described. Therefore, the rejection is maintained.

Remarks

Claims 2-5 are deemed free of the prior art of record because the prior art does not teach or reasonably suggest a nucleotide sequence having 90% sequence identity to SEQ ID NO: 3, a nucleotide sequence that hybridizes thereto under the specified

stringency conditions, or a nucleotide sequence comprising 200 contiguous bases of SEQ ID NO: 3, and encoding a polypeptide having peroxidase activity; nor that the prior art teaches an expression vector or a host cell comprising said nucleotide sequence.

No claim is allowed

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and After final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

3/15/04
Mai

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600